



**TULSA DENTAL PRODUCTS**

*Shaping The Future of Endodontics™*

K970134

**510(k) SUMMARY**

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TRADE NAME: THERMAPREP® PLUS OVEN

CLASSIFICATION NAME: Accessory to Gutta Percha      21 CFR, 872.3850

PREDICATE DEVICE: ThermaPrep® Oven      K910224

DEVICE DESCRIPTION: The THERMAPREP® PLUS OVEN is a heating unit for obturators. The system allows for individual heating of ThermaFil® gutta percha obturators. Microwave technology is used to produce uniform predictable heating results.

INTENDED USE: The THERMAPREP® PLUS OVEN is specially developed for heating ThermaFil® endodontic obturators. Do not use the oven for any other purpose.

TECHNOLOGICAL CHARACTERISTICS: The predicate device, ThermaPrep® Oven (K910224), heats ThermaFil® endodontic obturators by radiant heat. The new THERMAPREP® PLUS OVEN performs the same function by using microwave technology.

Various sizes of ThermaFil® endodontic obturators were heated using the THERMAPREP® PLUS OVEN and using the ThermaPrep® Oven (K910224). Results showed that heating times for all sizes of obturators were greatly reduced using the THERMAPREP® PLUS OVEN.

We believe that the performance data demonstrates the safety and effectiveness of the THERMAPREP® PLUS OVEN for its intended use.

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